

**United States Department of Agriculture
Animal and Plant Health Inspection Service
Center for Veterinary Biologics
P. O. Box 844
Ames, IA 50010**

1. **Reagent Name:** *Clostridium tetani* Antitoxin, 500 AU/mL
2. **Strain or Source:** Equine origin
3. **Lot Number:** IRP 445
4. **Fill Date:** December 23, 1998
5. **Expiration Date:** No expiration date has been assigned to this product because *E. tetanus* antitoxin has demonstrated over time to be very stable if properly stored. The stability of this reagent will be routinely monitored by the Center for Veterinary Biologics.

Precautions: There are no known hazards associated with the use of this reagent.

6. **Intended Use:** Equine tetanus antitoxin IRP 445 serves as the positive control serum when assaying the potency of equine tetanus antitoxin as outlined in 9 CFR 113.451 and **Supplemental Assay Method (SAM) 206**.

7. **Instructions for Use:** Use according to **SAM 206**.

8. **Test of Reagent:**

Determination of antitoxin titer - The antitoxin titer of IRP 445 was determined by the guinea pig toxin neutralization test as described in 9 CFR 113.451. The serum was found to contain 500 American antitoxin units (AU) per mL.

Sterility test - Five vials of IRP 445 were tested for sterility by inoculating them in sterile fluid thioglycollate medium and soybean-casein digest medium. No detectable growth appeared in any tubes of medium.

9. **Container Size, Type, Weight, or Volume:** Two-mL glass vials containing 1.2 mL of antitoxin.

10. **Storage Conditions:** Store at -25°C or lower.

11. CVB Technical Contact: Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.

12. Origin and Passage History: N/A

13. Method of Preparation: Equine serum containing at least 500 units of tetanus antitoxin per mL was mixed with serum from non-immunized horses using a ratio that provided 500 AU per mL. The serum mixture was filtered through a Millipore filtration unit containing a 0.22- μ m membrane, dispensed aseptically into sterile vials, and stored at $-70^{\circ}\pm 5^{\circ}\text{C}$. No preservatives were added to the serum.

14. Other: None

Reagent orders and feedback should be sent *including phone number* to the following email address: CVB@aphis.usda.gov

Reagent orders forms (APHIS 2018) are available from:
http://www.aphis.usda.gov/animalhealth/cvb_forms

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